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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,106	07/10/2001	Henrik Garoff	0825-0166P	8395
2292	7590	01/02/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 01/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

9.4

Office Action Summary

Application No.

09/901,106

Applicant(s)

GAROFF ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,45,51,52 and 63-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,45,51,52 and 63-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Detailed Action

The Oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective for the reasons of record in the previous Office Action (Mailed 4/1/03).

Applicants have responded to this requirement by indicating that they will submit a supplemental Declaration when the claims are otherwise in condition for allowance. Applicants also indicate that they do not concede that the presently claimed subject matter is not adequately disclosed in the parent PCT application PCT/SE91/00855. The requirement for a new Declaration is therefore maintained.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 43, 45, 51-52 and 63-71 are rejected under 35 U.S.C. 102(e) as

being anticipated by Johnson et al.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 43, 45, 51-52 and 63-71 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnson et al.

These rejections are maintained for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include newly presented claim 71.

Applicants traverse these rejections by asserting that the specification provides support for the claimed helper cells, alphavirus replicons, properties of the replicons, limitations of more than one helper RNA and characteristics of the helper RNAs. Applicants point to the specification on pp. 8-12, 15, original claims and Figs. 2, 4, 7C and 9.

Applicants' arguments presented 10/8/03 have been fully considered but are not persuasive.

With regard to the limitation of "helper cells", it is noted that the sections of the specification on pages 8-10 and Figs 7C and 9 pointed to by applicants only appear to recite **producer cells** which are **cotransfected** with the vector molecule and a helper RNA molecule so as to produce the recombinant alphavirus particles. Applicants do not recite the term "helper cell" in the specification and inclusion of this term would not be supported by the original specification.

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With regard to the limitation of alphavirus replicons, applicants have cancelled this term and substituted the term "recombinant alphavirus vector". This issue is now moot. It is noted that the replicons claimed by Johnson et al. fall within the definition of recombinant alphavirus vectors and are anticipated by Johnson et al.

With regard to the limitation of more than one helper nucleic acid, applicants only indicate that the specification can be construed to suggest to the skilled artisan that the helper RNA **can encompass** a plurality of helper RNAs encoding different structural proteins. Applicants indicate that wherein the alphavirus vector of original claim 13 includes deletions in multiple structural genes, those multiple structural genes could be on a plurality of helper DNA or RNA helper vectors to obtain all of the structural proteins for complementation. In response, the examiner notes that throughout the specification applicants refer to "**the** (emphasis added) helper RNA molecule" or "**the** (emphasis added) helper vector" and nowhere does the specification contemplate use of a plurality of different helper RNA molecules to supply *in trans* the structural proteins missing from the alphavirus vector.

With regard to the characteristics of the helper nucleic acids, applicants indicate that Fig. 7C shows an arrangement of all the genes encoding alphavirus structural proteins wherein all the genes are present on one helper vector. Applicants indicate that Fig. 4 shows that the E1 and E2 genes are present on one helper vector along with E1. With regard to the limitations of claim 45, applicants indicate that the specification teaches that E1, E2 and E3 are the spike structural proteins of the alphavirus and that a

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conditionally lethal mutation can be incorporated into a structural part of the alphavirus genome such as a region encoding viral structural proteins.

In response, the examiner notes that the claimed limitations of at least one helper RNA which includes at least one mutation in E1, E2 or E3 is not supported by the original specification as the term "at least one mutation" is a broad term meaning any number of any type of alteration (i.e. insertions, substitutions, deletions, point mutations, etc.) in the coding or non-coding regions of the E1, E2 or E3 sequences. The claims can read on a helper RNA comprising 1 or 5 or 10 or 100, etc. separate, unrelated, mutations in E1, E2 and/or E3. The original specification does not provide support for this limitation. With regard to applicants' indication that Fig. 7C shows an arrangement of all the alphavirus structural genes on a single vector, the examiner agrees with said assertion. However, the disclosure in Fig. 7C does not provide support for the claimed limitations of more than one helper RNA and mutations in E1, E2 or E3 in said helper.

With regard to the limitations of claim 65, the original specification provides no support for a helper cell comprising two separate helper RNAs wherein the first encodes E1 and E3 and the second encodes the alphavirus capsid protein.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The following is not described in the specification: The subject matter of claims 43, 45, 51-52 and 63-71 regarding helper cells, the limitations of more than one helper RNAs and the characteristics of the helper RNAs.

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No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. After January 14, 2004, the examiner can be reached at (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
December 29, 2003


DAVID GUZO
PRIMARY EXAMINER